

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Modified Constraint Induced Therapy versus Developmental Exercises on Reaching Capacity in Hemiplegic Children

#### Protocol summary

##### Study aim

To study the effect of developmental exercise therapy after removal of mCIMT on controlling upper limb spasticity in hemiplegic CP children.

##### Design

Randomized controlled trial

##### Settings and conduct

The motion analysis lab (Biomechanics Lab, College of Applied Medical Science, Prince Sattam bin Abdulaziz University).

##### Participants/Inclusion and exclusion criteria

Fifty-two hemiplegic children, ranging in age from four to six years ( $X \pm 6.4 \pm 3.5$  years) represented the sample of this study. They were selected from both sexes (26 females and 26 males) from the out-patient clinic of the Faculty of Physical Therapy, Cairo University, Egypt. The subjects enrolled in this study fulfilled the following criteria: [1] The degree of spasticity ranged from 1+ to 2 grades according to the modified Ashworth scale. [2] They were free from any associated disorders other than spasticity. [3] The affected upper limb was free from any structural deformities; however, patients demonstrated variable degree of tightness. [4] They had partial volitional control over the antispastic muscle groups. [5] They had normal superficial skin sensation of the affected upper limb. [6] All of them were within average IQ level.

##### Intervention groups

The children were divided randomly into two groups of equal number (I and II). Group I received developmental exercise therapy followed by a designed exercise program, while group II received mCIMT followed by the same exercise program given to group I.

##### Main outcome variables

Elbow extension and functional evaluation of reaching were measured before and after six months of the treatment program.

#### General information

##### Reason for update

##### Acronym

MCIT

##### IRCT registration information

IRCT registration number: **IRCT20210909052421N1**

Registration date: **2022-05-07, 1401/02/17**

Registration timing: **retrospective**

Last update: **2022-05-07, 1401/02/17**

Update count: **0**

##### Registration date

2022-05-07, 1401/02/17

##### Registrant information

##### Name

Nadia Radwan

##### Name of organization / entity

Prince Sattam Bin Abdulaziz University

##### Country

Saudi Arabia

##### Phone

+966 11 588 6500

##### Email address

n.radwan@psau.edu.sa

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-01-15, 1398/10/25

##### Expected recruitment end date

2021-01-15, 1399/10/26

##### Actual recruitment start date

2020-02-16, 1398/11/27

##### Actual recruitment end date

2021-04-16, 1400/01/27

##### Trial completion date

2021-12-15, 1400/09/24

## Scientific title

Modified Constraint Induced Therapy versus Developmental Exercises on Reaching Capacity in Hemiplegic Children

## Public title

Effect of Modified Constraint Induced Therapy on reaching capacity in Hemiplegic Children

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Hemiplegic children Ranging in age from four to six years  
The degree of spasticity ranged from 1+ to 2 grades according to the modified Ashworth scale. They were free from any associated disorders other than spasticity  
The affected upper limb was free from any structural deformities; however, patients demonstrated variable degree of tightness They had partial volitional control over the antispastic muscle groups. All of them were within average IQ level.

### Exclusion criteria:

The degree of spasticity ranged from 3to4 grades according to the modified Ashworth scale.

## Age

From **4 years** old to **6 years** old

## Gender

Both

## Phase

1-2

## Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

## Sample size

Target sample size: **55**

Actual sample size reached: **52**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Simple randomization. This technique maintains complete randomness of the assignment of a subject to a particular group. The method of simple randomization used is flipping a coin. For example, with two treatment groups (control versus treatment), the side of the coin (i.e., heads - control, tails - treatment) determines the assignment of each subject.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

The participant, care provider, and the data collectors are unaware of the treatment the participant receives.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Prince Sattam Bin Abulaziz university

##### Street address

ALmanifeia, Alraghi building

##### City

Alkharj

##### Postal code

00966

#### Approval date

2021-04-22, 1400/02/02

#### Ethics committee reference number

RHPT/021/010

## Health conditions studied

### 1

#### Description of health condition studied

hemiplegic children

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Elbow extension and upper limb kinematics ( movement time, peak velocity, time-to-peak velocity, percent of reach-to-peak velocity, number of movement units, percent of time of first movement unit) were the outcome variables

#### Timepoint

Elbow extension and functional evaluation of reaching were measured before and immediately after six months of the treatment program.

#### Method of measurement

Electro-Goniometer and 3-Dimensional motion analysis system

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: who received modified constraint movement therapy

#### Category

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

King Khalid Hospital

**Full name of responsible person**

Radwa S. Abdul-Rahman

**Street address**

ALmanifeia, Alraghi building

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n.radwan@psau.edu.sa

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

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**Full name of responsible person**

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**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Prince Sattam Bin Abdulaziz University

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

Academic

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**

Prince Sattam Bin Abdulaziz University

**Full name of responsible person**

Radwa Said

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no further information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available